Development and Characterization of UHMWPE Fiber-Reinforced Hydrogels for Meniscal Replacement

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Abstract

Meniscal tears are the most common orthopedic injuries to the human body. The current treatment of choice, however, is a partial meniscectomy and leads to osteoarthritis proportional to the amount of tissue removed. As a result, there is a significant clinical need to develop materials capable or restoring the biomechanical pressure distribution to the knee after meniscectomy and preventing the onset of osteoarthritis. In this work, a fiber-reinforced hydrogel-based synthetic meniscus was developed that allows for tailoring of the mechanical properties and molding of the implant to match the size, shape, and property distribution of the native tissue.

Physically cross-linked poly(vinyl alcohol) (PVA) hydrogels were reinforced with ultra high molecular weight polyethylene (UHMWPE) fibers and characterized in compression (0.1 - 0.8 MPa) and tension (0.1 - 250 MPa) showing fine control over mechanical properties based on PVA concentration, UHMWPE fiber volume fraction, and hydrogel freeze-thaw cycles within the range of the human meniscus. Morphology and crystallinity analysis of PVA hydrogels showed increases in crystallinity and PVA densification, or phase separation, with freeze-thaw cycles. A comparison of freeze-thawed and aged physically cross-linked hydrogels provided insight on both crystallinity and phase separation as mechanisms for PVA gelation. Results indicated both mechanisms independently contributed to hydrogel modulus for freeze-thawed hydrogels.

In vitro swelling studies were performed using osmotic solutions to replicate the swelling pressure present in the knee. Minimal swelling was observed for hydrogels with a PVA concentration of 30-35 wt%, independently of hydrogel freeze-thaw cycles. This allows for independent tailoring of hydrogel modulus and pore structure using freeze-thaw cycles, and swelling behavior using polymer concentration to match a wide range of properties needed for various soft tissue applications.

The UHMWPE-PVA interface was identified as a significant weakness. To improve interfacial adhesion a novel biocompatible PVA grafting technique was developed to form a direct covalent linkage at the fiber-matrix interface. Chemical grafting was tailored as a function of the number of sites available for covalent bonding and the percentage of sites reacted. Interfacial adhesion was characterized by measuring interfacial shear strength using fiber pull- out tests. PVA grafting resulted in significant improvements to interfacial shear strength from 11 kPa without any

treatment to above 220 kPa following grafting. After grafting, failure was observed cohesively within the PVA hydrogel indicating the UHMWPE-PVA interface was successfully optimized. Inter-fiber spacing also had a significant effect on interfacial shear strength.

Lastly, *in vitro* gait simulations and an *in vivo* sheep study demonstrated the feasibility and biocompatibility of the proposed UHMWPE-PVA composite. The results from this work can be applied to designing materials for other soft tissue applications, including the ACL and the annulus fibrosus.